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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/739,289	12/19/2000	Luc Montagnier	3495.0068-10	3312

22852 7590 07/15/2003

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
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EXAMINER

PARKIN, JEFFREY S

ART UNIT PAPER NUMBER

1648

DATE MAILED: 07/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/739,289

Applicant(s)

MONTAGNIER ET AL.

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2000 and 20 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

- 4) ☒ Claim(s) 21-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Detailed Office Action

Status of the Claims

1. Acknowledgement is hereby made of receipt and entry of the preliminary amendments filed 19 December, 2000, and 20 August, 2002, wherein claims 1-20 were canceled without prejudice or disclaimer and new claims 21-38 submitted.

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Information Disclosure Statement

2. The information disclosure statements filed 19 March, and 27 April, 2001, have been placed in the application file and the information referred to therein has been considered.

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37 C.F.R. § 1.75(c)

3. Claim 30 is objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim. The claim references an HIV-2 antigen, gp300, which comprises two gp140 monomers. The gp300 antigen is a dimeric form of gp140, therefore this antigen must contain the two gp140 monomers. Refer to M.P.E.P. § 608.01(n).

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35 U.S.C. § 112, Second Paragraph

4. Claims 31 and 32 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims contain the phrase "substantially unglycosylated protein" which is vague and indefinite since the precise degree of glycosylation can not be ascertained. For instance, is a protein that retains 3% of the original carbohydrate groups considered substantially unglycosylated? What about other ranges such as 5%, 7%, 10%, 20%, or 25%? The disclosure fails to

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provide a detailed definition of this term. Accordingly, the metes and bounds of the patent protection desired can not be determined.

35 U.S.C. § 102

5 5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

10 (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of
15 this title before the invention thereof by the applicant for patent.

6. Claims 21-24 and 27-32 are rejected under 35 U.S.C. § 102(e) as being anticipated by Montagnier et al. (1997) as evidenced by Walsh et al. (1985), Earl et al. (1990), and McGuire et al. (1992).
20 Montagnier et al. (1997) disclose monoclonal and polyclonal immunological reagents that recognize HIV-2 gp130-140. This antigen is the monomeric form of the HIV-2 envelope glycoprotein. It has been well-established that both polyclonal and monoclonal immunological reagents that are generated against monomeric viral
25 envelope glycoproteins routinely recognize multimeric forms of the protein (as evidenced by Walsh et al., 1985; Earl et al., 1990; McGuire et al., 1992). Therefore, one of ordinary skill in the art would reasonably expect polyclonal and monoclonal reagents directed against HIV-2 gp130-140 to also bind and recognize dimeric forms of
30 the protein. This result is not surprising considering the numerous immunodominant epitopes shared by both species.

7. Claims 33, 36, and 37 are rejected under 35 U.S.C. § 102(e) as being anticipated by Kanki et al. (1985) as evidenced by Walsh et
35 al. (1985), Earl et al. (1990), and McGuire et al. (1992). Kanki

et al. (1985) provide polyclonal immunological reagents that recognize the SIV envelope glycoprotein gp160/gp120. These antigens are the monomeric form of the SIV envelope glycoprotein. It has been well-established that both polyclonal and monoclonal immunological reagents that are generated against monomeric viral envelope glycoproteins routinely recognize multimeric forms of the protein (as evidenced by Walsh et al., 1985; Earl et al., 1990; McGuire et al., 1992). Therefore, one of ordinary skill in the art would reasonably expect polyclonal reagents directed against SIV gp160/gp120 to also bind and recognize dimeric forms of the protein. This result is not surprising considering the numerous immunodominant epitopes shared by both species.

35 U.S.C. § 103(a)

8. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of

the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

10. Claims 25 and 26 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Montagnier et al. (1997) in view of Galfrè and Milstein (1975). As disclosed *supra*, this teaching provides monoclonal and polyclonal reagents that are specific to the HIV-2 envelope glycoprotein. This teaching does not disclose labeled antibodies. However, Galfrè and Milstein (1975) provide detailed methodologies for labeling antibodies to facilitate their use in immunodiagnostic assays (e.g., see pp. 26-28). Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to label the HIV-2 Env-specific reagents provided by Montagnier et al. (1997) as taught by Galfrè and Milstein (1975).

11. Claims 34, 35, and 38 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kanki et al. (1985) in view of Galfrè and Milstein (1975). As disclosed *supra*, this teaching provides polyclonal reagents that are specific to the SIV envelope glycoprotein. This teaching does not disclose the preparation of monoclonal reagents or labeled antibodies. However, Galfrè and Milstein (1975) provide detailed methodologies for the preparation of monoclonal reagents and labeling protocols to facilitate their use in immunodiagnostic assays (see entire document). Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to label the SIV Env-specific reagents provided by Kanki et al. (1985) as taught by Galfrè and Milstein (1975). It would also have been *prima facie*

obvious to one having ordinary skill in the art at the time the invention was made to prepare monoclonal reagents to the SIV Env as taught by Galfrè and Milstein (1975) since this would provide a source of highly specific immunological reagents.

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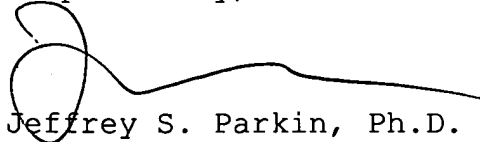
Correspondence

12. The Art Unit location of your application in the Patent and Trademark Office has changed. To facilitate the correlation of related papers and documents for this application, all future
10 correspondence should be directed to **art unit 1648**.

13. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette,
15 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax
20 number: (703) 308-4426. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

14. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-
25 2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, Laurie Scheiner or James Housel, can be reached at (703) 308-1122 or (703) 308-4027,
30 respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,



Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

10 July, 2003